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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,158	08/25/2003	Kenneth MC Cheung	UHK-118XT	3550
23557	7590	12/10/2008	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			SHAFFER, RICHARD R	
		ART UNIT	PAPER NUMBER	
		3775		
		MAIL DATE		DELIVERY MODE
		12/10/2008		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/648,158	CHEUNG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Richard Shaffer	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 September 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 20-22,28,29 and 32-49 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 20-22,28,29 and 32-49 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input checked="" type="checkbox"/> Other: <u>Rahman (2008)</u> .

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 30<sup>th</sup>, 2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-22, 28, 29 and 32-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 20 and 36 recite the limitation, "a transition temperature within the range of body temperature of the patient" and independent claim 36 recites, "the superelastic material having a transition temperature within the range of the recipient's body temperature." Applicant does not have support as originally filed for stating that the device has a transition temperature within the range of the patient/recipient. Applicant does have

support as originally filed in original claim 25 which states, “human body temperature.” It is recommended that should applicant wish to further limit the reference to which the transition temperature is made in, to use the word “human” instead of patient or recipient.

All dependent claims are rejected for containing the new matter limitation through dependence.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-22, 28, 29 and 32-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's recitation of “transition temperature” in all the independent claims and in the remaining claims through dependence is ambiguous as evidenced by Rahman (Patents on Superelastic Shape Memory Alloy, 2008). There are four standard temperatures which are referred to as transition temperatures for shape memory alloys such as Nitinol, they are  $M_f$ ,  $M_s$ ,  $A_s$  and  $A_f$ . Since applicant is using the superelastic properties of a shape memory alloy, it would be either  $A_s$  or  $A_f$  or any temperature inbetween or above, but it is unclear which applicant is referring to in the claim and therefore causes the claims to be indefinite.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-22, 28, 29 and 32-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drewry et al (US Patent 6,783,527).

Drewry et al disclose a method for correcting spinal deformities comprising: providing a constant (and controllable dependent upon the surgeon's original tension/deformation of the superelastic material) correction force through the use of tethers **(80)** made of superelastic Nitinol (**Column 3, Lines 60-65**) which generates the correction force at body temperature; the forces activated during surgery (inherent due to the material being tensioned - **See Column 4, Lines 1-2** - to cause an elastic response) and are adjusted/set by tensioning the tethers **(80)** by the surgeon. The tethers **(80)** are anchored by elements **(30 and 50)** that are formed of Nitinol (**Column 4, Line 66 through Column 5, Line 6**) which limit rotational movement of the tether. The overall device can be placed anteriorly or posteriorly (**Column 3, Lines 48-55**). The device is deformed to conform to the spinal deformities (inherent due to it being tensioned and anchored to the vertebrae).

Drewry et al fail to disclose that the Nitinol in the superelastic tether **(80)** has a transition temperature within the range of the patient's/recipient's body temperature. As evidenced by Rahman, a stress-induced phase transformation from austenite to martensite is required for superelasticity to exist. Therefore, any temperature greater than  $A_s$  would contain an austenitic crystal structure (with anything greater than  $A_f$  being

all austenite) to be deformed into martensite to yield superelastic properties. It would have been an obvious to one having ordinary skill in the art at the time the invention was made to select a transition temperature to be within a patient's/recipient's body temperature range, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

***Response to Arguments***

Applicant's arguments with respect to the amended claims have been considered and are persuasive with regard to Cool et al and Sanders et al references but are largely moot with regard to Drewry et al in view of the new ground(s) of rejection.

Applicant's relevant arguments given the new grounds of rejection under Drewry include the contention that Drewry et al relies on the elastic characteristics of the material in generating a corrective force, not superelastic characteristics. This is not found persuasive due to a superelastic material not being superelastic without existing in a temperature where the austenite phase exists and being deformed to cause a crystal lattice change to martensite. Therefore, any strain recovery is due to the superelastic properties, not mere elastic properties. Drewry et al even state as applicant has pointed out that the tether is tensioned in order to generate a corrective force, and since the tether is superelastic in the austenite phase, it meets the claimed invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/  
Examiner, Art Unit 3775  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733